

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

*SEARCHED & INDEXED*  
*NOV 12 2003*  
*U.S. PATENT & TRADEMARK OFFICE*  
In re U.S. Patent Application of

Lola M. REID *et al.*

Patent Application No.: 10/645,610

Filed: August 22, 2003

Title: PROLIFERATION OF HEPATOCYTE PRECURSORS

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT UNDER**  
**37 C.F.R. § 1.56, § 1.97(b)(3) AND § 1.98**

In compliance with the duty of disclosure under 37 C.F.R. § 1.56 and in accordance with the practice under 37 C.F.R. § 1.97 (b)(3) and § 1.98, Applicants bring to the attention of the Examiner the documents listed on the attached Form PTO/SB/08A. This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits for the above-referenced application.

Copies of the documents were previously submitted in Patent Application No. 09/534,487 filed March 24, 2000, from which this application claims priority under 35 U.S.C. § 120. Accordingly, no copies are being provided herewith.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each, any, or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in the present application and Applicants determine that the cited documents do not constitute "prior art" under United States law, Applicants reserve the right to present to the office the relevant facts and law regarding the appropriate status of such documents. Further, Applicants reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied as prior art against the claims of the present application.

**CONCLUSION**

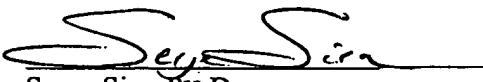
It is respectfully requested that the attached information be considered by the Examiner and that a copy of the attached Form PTO/SB/08A be returned indicating that such information has been considered.

Applicants' undersigned attorney may be reached in our Washington, D.C. office by telephone at (202) 625-3500. All correspondence should continue to be directed to our address given below.

**AUTHORIZATION**

Applicants believe there is no fee due in connection with this filing as this Information Disclosure Statement is being filed prior to any Office Action on the merits in this matter. However, to the extent required, the Commissioner is hereby authorized to charge any fees due in connection with this filing to Deposit Account 50-1710 or credit any overpayment to same.

Respectfully submitted,



Serge Sira, PH.D.  
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Dated: November 12, 2003

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**C mplete if Known**

Application Number	10/645,610
Filing Date	August 22, 2003
First Named Inventor	Lola M. REID et al.
Art Unit	unassigned
Examiner Name	unassigned

Attorney Docket Number 320727-00123

**U. S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> ( <i>if known</i> )			
gw	1	US- 5,087,570	02/11/92	Weissman, et al.	
	2	US- 5,061,620	10/29/91	Tsukamoto, et al.	
	3	US- 5,030,105	07/09/91	Kuri-Harcuch, et al.	
	4	US- 5,576,207	11/19/96	Reid, et al.	
	5	US- 5,858,721	01/12/99	Naughton et al.	
	6	US- 5,785,964	07/28/98	Naughton et al.	
	7	US- 5,624,840	04/29/97	Naughton et al.	
	8	US- 5,510,254	04/23/96	Naughton et al.	
	9	US- 5,160,490	11/03/92	Naughton et al.	
	10	US- 5,032,508	07/16/91	Naughton et al.	
gw	71	US- 5,789,246	08/04/98	Reid et al.	
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**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> ( <i>if known</i> )				
gw	11	WO 94/08598	04/28/94	ADVANCED TISSUE SCIENCES INC		

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**NON PATENT LITERATURE DOCUMENTS**

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SV	12	Agelli et al. "Survival in Culture of Putative Liver Stem Cells is Independent from Known Epithelial Cell Growth Factors", Clinical Research, Vol 39, No. 2, pp. 167A 1991.	
	13	Armentano, et al. Expression of human Factor IX in rabbit Hepatocytes by Retrovirus-Mediate Gene transfer: Potential for gene Therapy of Hemophilia B", Proc. Natl. Acad. Sci.", Vol. 87, pp. 6141-6145, (1990)	
	14	ATERMAN, "The Stem Cells of a Liver-a Selective Review", J Cancer Research Clinical Oncol", Vol. 118. pp. 87-115 (1992)	
	15	BARCLAY, "The Localization of Populations of Lymphocytes defined by Monoclonal Antibodies in Rat Lymphoid Tissues", Immunology, Vol. 42, PP. 593-600 (1981)	
	16	Bauvois et al. "Inhibition of $\gamma$ -Glutamyl Transpeptidase Activity at the Surface of Human Myeloid Cells Is Correlated with Macrophage Maturation and Transforming Growth Factor B Production", Cell Growth & Differentiation, Vol. 6, pp. 1163-1170 1995.	
	17	BLOCK et al. "Population Expansion, Clonal Growth, and Specific Differentiation Patterns in Primary Cultures of Hepatocytes Induced by HGF/SF, EGF and TGF @ in a Chemically Defined (HGM) Medium", Journal of Cell Biology, Vol. 132, No. 6, pp. 1133-1149, 1996	
	18	BRILL et al., "Maturation-Dependent Changes in the Regulation of Liver-Specific Gene Expression in Embryonalversus Adult Primary Liver Cultures", Differentiation, Vol. 59, pp. 95-102.	
	19	BRILL et al. Extracellular Matrix Regulation of Growth and Gene Expression in Liver Cells Lineages and Hepatomas", The Liver: Biology and Pathobiology", pp. 869-891, 1994	
	20	CHOMCZYSKI et al., "Single-Step Method of RNA Isolation by Acid Guanidinium Thiocyanate-Phenol-Chloroform Extraction", Anal. Biochem., Vol. 162. pp. 156-159 1987.	
	21	Cronrad et al., "Combined Cystic Teratoma and Hepatoblastoma of the Liver" Cancer, Vol. 72, (No. 10), pp. 2910-2913 1993.	

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Attorney Docket Number	320727-00123

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Q.W	32	GRISHAM, "Migration of Hepatocytes Along Hepatic Plates and Stem Cell-Fred Hepatocyte Lineages", "American J. of Pathology", Vol. 144 (No.5), pp. 849-854 (1994)	
	33	GRISHAM et al., "Isolation, Culture and Transplantation of Rat Hepatocytic Precursor (Stem-Like) Cell, "Culture of Hepatocytic Stem-Like Cells", Vol. 204 (No. 3), pp. 270-279 (1993)	
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	36	HIXON et al., "An antigenic Portrait of the Liver during Carcinogenesis", Pathbiology: Liver Carcinogenesis", pp. 65-77 (1990)	
	37	HOANG et al., "Separation Hemopoietic Cells From Adult Mouse Marrow by use of Monclonal Antibodies", Monoclonals Against Hemopoietic Cells", Vol. 61, pp. 580-588 (1983)	
	38	JOHE et al., "Single Factors Direct the Differentiation of Stem Cells from the Fetal and Adult Central Nervous System", Genes & Development", vol 10, pp. 3129-3140 (1996)	
	39	KOCH, et al., "Retroviral Vector Infection and Transplantation in Rats of Primary Fetal Rat Hepatocytes", Journal of Cell Sciences", Vol. 99, pp. 121-130 (1991)	
	40	LAFANGE-FRAYSSINET et al., "Alpha-Fetoprotein Gene Expression in Human Lymphoblastoid Cells and in Pha-Stimulated Normal T-Lymphocytes", Biochemical and Biophysical Research Communications", Vol. 159, No. 1, pp. 112-118 (1989)	
	41	LEDLEY et al., "Retroviral Gene Transfer Into Primary Hepatocytes: Implication for Genetic Therapy of Liver-Specific Functions", Proc. Natl. Acad. Sci., Vol. 84, pp. 5335-5339 (1987)	

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✓	42	LEH, et al. "Cloning and Expression of a Novel Type (III) of Human $\gamma$ -Glutamyltransferase truncated mRNA," FEBS Letters, Vol. 394, pp 258-262. (1996)	
	43	LI et al. "Culturing of Primary Hepatocytes as Entrapped Aggregates in a Packed Bed Bioreactor: A Potential Bioartificial Liver", In Vitro Cell. Dev. Bio., Vol. 29A, pp. 249-254 (1993)	
	44	MORAN et al., "Hepatoid Yolk Sac Tumors of the Mediastinum: A Clinicopathologic and Immunohistochemical Study four Cases", The Amer. Journal of Surgical Pathology, Vol. 21 No. 10, pp. 1210-1214, (1997)	
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	46	PRETLOW et al., (eds) Cell-Separation: Methods and Selected Applications, pgs. 45-77 Academic Press, New York (1987)	
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	50	RUCK et al., "Hepatic Stem-Like Cells In Hepatoblastoma: Expression Cytokeratin 7, Albumin and Oval Cell Associated Antigens Detected by OV-1 and OV-6", Histopathology, Vol. 31, pp. 324-329 (1997)	
	51	RUTENBERG et al., "Histochemical and Ultrastructural Demonstration Glutamyl Transpeptidase Activity", Journal of Histochemistry and Cytochemistry.", Vol. 17, pp. 517-526 (1969)	

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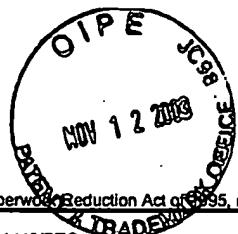
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✓	52	SANDERS et al., "Determination of Guanine-Plus-Cytosine Content of Bacterial DNA by Dual-Laser Flow Cytometry", Journal of General Microbiology", Vol. 136 (Part 2), pp. 219-376 (1990)	
	53	SANDERS et al., "Detection and Analysis by Dual-Laser Flow Cytometry of Bacteriophage T4 DNA Inside Escherichia Coli", Journal of the Inter. society for Analytical cytology Cytometry", Vol. 12, pp. 167-171 (1991)	
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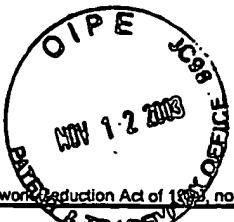
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7u	62	STEINKAMP et al., "A New Multiparameter Separator for Microscopic Particles and Biological Cells", Review of Scientific Instruments", Vol. 44 (No. 9), pp. 1301-1310 (1973)	
	63	TANIGUCHI et al., "Conditions for the Successful Engraftment of Hepatocyte Progenitors Injected into the Spleen", Transplantation Proceedings, Vol. 28 (No. 3), pp. 1855-1856,	
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	66	TSUCHIDA, et al., "The Role of Subfractionation of Alpha-Fetoprotein in the Treatment of Pediatric Surgical Patients", J. of Pediatric Surgery', Vol. 32, No. 3, pp. 514-517 (1997)	
	67	WILSON et al., "Temporary Amelioration of Hyperlipidemia in Low Density Lipoprotein Receptor-Deficient Rabbits Transplanted with Genetically Modified Hepatocytes", Proc. Natl. Acad. Sci. : Vol. 87, pp. 8437-8440 (1990)	
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	70	Yamamasu, et al., "Role of Glutathione Metabolism and apoptosis in the Regression of Live Hemopoiesis", Free Radical Biology & Medicine, Vol. 23 (No. 1) pp. 100-109 (1997)	

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